

Notice of Allowability

Application No.

09/993,976

Examiner

Abigail M. Cotton

Applicant(s)

YATVIN ET AL.

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to documents received 8/29/2005 and 12/9/2005.
2. ☒ The allowed claim(s) is/are 1,3-5 and 7-9.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kevin Noonan on December 5, 2005.

The application has been amended as follows:

In claim 1, line 8, after "benzodiazapene" please **delete** "antidepressants" and **insert** "antidepressant" therefore.

In claim 1, line 15, after "(c) a spacer having" please **delete** "two linker functional groups and" and **insert** "a first linker functional group and a second linker functional group," therefore.

In claim 1, line 17, after the first instance of "wherein" please **insert** "the spacer has a first end and a second end and".

In claim 1, line 17, after the second instance of "wherein" please **delete** "the amino acid or amino acid derivative" and **insert** "5-hydroxytryptophan, serotonin, or melatonin" therefore.

In claim 1, line 18, after "is attached to the" please **delete** "spacer through a first linker" and **insert** "first end of the spacer through the first linker" therefore.

In claim 1, line 19, after "is attached to the" please **delete** "spacer through a second linker" and **insert** "second end of the spacer through the second linker" therefore.

In claim 7, line 8, after "benzodiazapene" please **delete** "antidepressants" and **insert** "antidepressant" therefore.

The following is an examiner's statement of reasons for allowance:

Claims 1, 3-5 and 7-9 are allowable because the prior art of record does not teach or suggest a pharmaceutical composition comprising the (i) claimed drug, (ii) 5-hydroxytryptophan, serotonin or melatonin, and (iii) a spacer, wherein the spacer has first and second linker functional groups, and first and second ends, and wherein the 5-hydroxytryptophan, serotonin, or melatonin is attached to the first end of the spacer through the first linker functional group, and the drug is attached to the second end of

the spacer through the second end of the second linker functional group, as in claim 1.

The prior art of record also does not teach or suggest a pharmaceutical composition comprising (i) the claimed drug having a first linker functional group, and (ii) 5-hydroxytryptophan, serotonin or melatonin having a second linker functional group, wherein the drug is covalently linked to 5-hydroxytryptophan, serotonin or melatonin by a chemical bond between the first and second linker functional groups, as in claim 7.

The closest prior art of record is U.S. Patent No. 5,827,819 to Yatvin et al, issued October 27, 1998. The Yatvin et al. patent teaches a technology for facilitating the rapid and efficient introduction of agents across the blood-brain barrier by providing a psychotropic, neurotropic or neurological drug that is linked to a polar lipid carrier, optionally through a spacer, and wherein the polar lipid carrier comprises a polar lipid such as sphingosine, ceramide, phosphatidyl choline and acyl carnitine (see abstract and claims 1 and 6-7, in particular.) The Yatvin et al. patent does not teach or suggest linking a drug, with or without a spacer, to a carrier that is 5-hydroxytryptophan, serotonin or melatonin. Accordingly, as the prior art of record does not teach or suggest the combination of the claimed drugs linked to 5-hydroxytryptophan, serotonin or melatonin, with or without a spacer, claims 1, 3-5 and 7-9 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

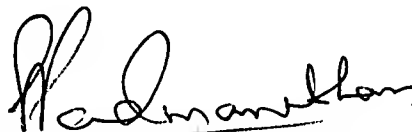
accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMC


SREENIVASAN PADMANABHAN
SUPERVISORY PATENT EXAMINER